UNITED STATES PATENT AND TRADEMARK OFFICE

AUG 24 2005

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, N.W.
Washington DC 20005-3934

In re Application of
Foster et al.
Serial No. : 09/937,484
Filed : 2 January 2002
Attorney Dkt No. : 1581.0870000/RWE/ALS

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144 and 1.181, filed on 17 August 2004, to withdraw the lack of unity requirement. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed under 35 USC 371 on January 2, 2002 with 17 claims (claims 30-47) drawn to a conjugate of lectin and a peptide/protein, a nucleic acid encoding said conjugate and peptide and methods of there use and preparation. After an initial lack of unity requirement mailed on October 3, 2003, a second supplemental lack of unity requirement was mailed on January 29, 2004 in which claims 30-47 were divided in to ten groups based on 35 U.S.C. 121 and 372, as follows:

> Group I, claims 30-37, drawn to a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 530, subclass 300+.
>
> Group II, claim 38 drawn to a nucleic acid sequence encoding a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 435, subclass 5+.
>
> Group III, claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of a lectin, classified in class 514, subclass 2.

Group IV, claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of a nucleic acid sequence coding a lectin, classified in class 514, subclass 2.
Group V, claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 514, subclass 2.

Group VI, claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of a nucleic acid sequence encoding a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity), classified in class 514, subclass 2.

Group VII, claims 43-44, drawn to a method of preparing a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity) comprising coupling the compounds together, classified in class 424, subclass 1.69+.

Group VIII, claims 43-44, drawn to a method of preparing a conjugate of lectin (non-endogenous to humans) and a peptide/protein (substantially free of Clostridial neurotoxin enzyme activity) comprising expressing in a host cell a nucleic acid sequence capable of encoding said conjugate, classified in class 424, subclass 1.69+.

Group IX, claims 45-46, drawn to a lectin AND a peptide or protein (AS OPPOSED TO A CONJUGATE of the two compounds), classified in class 530, subclass 300+.

Group X, claim 47, drawn to a method of treating a disease or condition comprising administering a lectin AND a peptide or protein (AS OPPOSED TO A CONJUGATE of the two compounds), classified in class 514, subclass 2.

Applicants elected with traverse to prosecute the invention of Group III, represented by claims 39-42, drawn to a method of treating a disease or condition comprising administering an effective amount of a lectin and the specific conjugate comprising *Erythrina cristagalli* lectin.

A first action on the merits was mailed on June 21, 2004 in which Examiner rejected claims 39-42 under 35 U.S.C. 112, 2nd paragraph as unclear how an *Erythrina cristagalli* lectin conjugate can both inhibit and stimulate C-fiber activity, in order to treat a disease or condition resulting from an inhibition or stimulation of C-fiber neuron activity, asking the applicant to point out where in the specification support may be found for both types of modulation by an *Erythrina cristagalli* lectin conjugate, or amend the claims to more distinctly claim the invention. Additionally, the Examiner suggested that Applicant amend the claims to distinctly claim only the elected invention.

Claims 39-41 were rejected under 112 second paragraph. Claims 39-42 were also rejected in the same Office action under 35 U.S.C. 112, 1st paragraph as not enabled and not described.

Applicants filed the instant petition on August 17, 2004.

On September 21, 2004 applicants responded to the first action on the merits by canceling claims 30-47 and adding new claims 48-61 drawn to a method of inhibiting C-fiber neuron activity, comprising administering to a patient a first lectin in amount effective to inhibit C-fiber neuron activity, wherein the first lectin is selected from the group consisting of a lectin that binds to a galactosyl residue and a lectin that binds to a glucosyl residue.

DISCUSSION

The petition under 37 C.F.R. 1.144 and 1.181, was filed on 17 August 2004, to withdraw the lack of unity requirement. Specifically applicants petition the lack of unity requirement on the basis that:

A) Federal Regulations and PCT Administrative Instructions Demonstrate that Lack of unity is Improper,

B) Examination of all of the Claims is not burdensome,

C) Federal Courts regard lack of unity of a single claim as improper, and

D) additional comments responsive to the examiner's supplemental lack of unity requirement.

In the analysis of the fact pattern of the prosecution of the instant application, it is noted that applicants have cancelled claims 30-47 which the lack of unity requirement in question was based upon and applicants have substituted those claims with claims 48-61 drawn to a method of inhibiting C-fiber neuron activity, comprising administering to a patient a first lectin in amount effective to inhibit C-fiber neuron activity, wherein the first lectin is selected from the group consisting of a lectin that binds to a galactosyl residue and a lectin that binds to a glucosyl residue. It is noted that all of the newly submitted claims 48-62 would fall within the previously elected group III, however applicants' arguments which are drawn to the propriety of the lack of unity requirement are addressed.

Applicants petition the lack of unity requirement as stated above as it applies to the previous claims 30-47 on the basis that Federal Regulations and PCT Administrative Instructions Demonstrate that Lack of unity is improper on the basis that the instant application has entered the national stage from an international stage application after compliance with 35 U.S.C. 371 and that all of the claims possess unity of invention because they contain the same special technical feature. Applicants submit that the special technical feature of the claims should be construed as medicinal lectins and that this feature is present in independent claims 30 and 45.

Applicants' argument is acknowledged, however, found not persuasive on the basis that the shared special technical feature of each of the groups is not a "medicinal lectin", but rather a lectin, as this is the only technical feature shared between each of the previously identified ten groups. As stated by the examiner, the inventions listed as Groups I through X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I through X share a technical relationship which corresponds to a lectin. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. As previously stated, Mathiowitz (US 6,235,313 B1) teach the use of a lectin from *Erythrina cristagali* in a composition with a peptide for treatment of inflammation. Thus, the shared technical feature of the groups is not a "special technical feature", as it makes no contribution as a whole over the prior art and unity of invention between the groups cannot be based upon known features.

Applicants further petition on the basis that Federal Regulations and PCT Administrative Instructions Demonstrate that Examination of all of the Claims is not burdensome, because the application was considered to have unity of invention during the international phase. This argument is not found persuasive on the basis that decisions regarding unity of invention during the international phase are not binding to the application during the national phase and unity is reconsidered anew at each stage of the prosecution. As stated above, the different groups indicated by the examiner lack unity of invention because they do not share a "special technical feature" as discussed above.

Applicants' argument on the basis that Federal Courts regard lack of unity within a single claim as improper, based on *In re Weber*, 198 U.S.P.Q. 332 (CCPA 1978) and *In re Hass*, 198 U.S.P.Q. 334 (CCPA 1978) is acknowledged, however, not found persuasive on the basis that the applications referred to in these cases which were not filed under 35 USC 371, are not directed to lack of unity practice. Moreover, the determination of unity of invention does not depend upon the inventions being in the same or separate claims. See 37 CFR 1.475(e) below.

> (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Finally, applicants argue that the examiner has misconstrued the special technical feature and used US 6,235,313, to defeat "lectin". Applicants submit that such action is misplaced as the '313 patent does not describe the use of any lectin as a medicament. This argument is not found persuasive on the basis that the shared technical feature

between all of the groups is not a "medicinal lectin" but rather a "lectin". Moreover, because Mathiowitz (US 6,235,313 B1, see column 10, lines 60-67, claim 2 and Abstract) teach the use of a lectin from *Erythrina cristagali* in a composition with a peptide for treatment of inflammation, a medicinal use, this technical feature is not a special technical feature.

As stated above, applicants have cancelled claims 30-47 which the lack of unity requirement in question was based upon and replaced those claims with claims 48-62 drawn to a method of inhibiting C-fiber neuron activity, comprising administering to a patient a first lectin in an amount effective to inhibit C-fiber neuron activity, wherein the first lectin is selected from the group consisting of a lectin that binds to a galactosyl residue and a lectin that binds to a glucosyl residue. It is noted that all of the newly submitted claims 48-61 would fall within the previously elected Group III and have all been examined.

DECISION

Because the technical feature that links the original inventions is not a contribution over the prior art in view of Mathiowitz, the petition under 37 C.F.R. 1.144 and 1.181, filed on 17 August 2004, to withdraw the lack of unity requirement as to claims 30-47 is **DENIED**.

The application will be forwarded to the examiner for consideration of the amendment filed 21 September 2004.

Because there is no fee for this petition, the petition fee paid of $130.00 will be credited to applicants' Deposit Account No. 19-0036, as directed.

Any request for consideration of this petition decision must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.

Bruce Kisluik
Director, Technology Center 1600